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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,776	11/13/2003	Richard S. Sanders	279.651US1	7410

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT	PAPER NUMBER
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3762

MAIL DATE	DELIVERY MODE
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05/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,776	SANDERS, RICHARD S.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 57-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 57-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060623</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments, see "Remarks", filed 9/14/2007, with respect to the rejection(s) of claim(s) 1-10 under 35 USC 102 and 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of new art.

Election/Restrictions

2. Applicant's election without traverse of claims 1-10 in the reply filed on 2/8/2007 is acknowledged.
3. Claims 11-56 are cancelled.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

The "duty to disclose" clause should read: "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56.", not "I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56"

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 6-10, 61, 65, and 66 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine (US 6,477,417, hereinafter "Levine").

7. In regards to claim 1, Levine discloses a sensing circuit (82, 84 and 108), a pacing circuit (70 and 78), and a processor that is upgradeable from a cardiac monitor controller to a cardiac pacemaker controller wherein the sensing circuit is adapted to be programmed from a far-field sensing configuration to an intracardiac electrogram sensing configuration (col. 2, line 2). Examiner is interpreting Levine's device in the unipolar mode to comprise a cardiac monitor controller because it has monitoring functionality and a pacemaker controller in the bipolar configuration because it has pacing functionality.

8. In regards to claim 6, the device comprises RAM containing control code (col. 9, line 54).

9. In regards to claim 7, the device comprises an activity sensor (col. 14, line 35).

10. In regards to claim 8, an electrogram is stored (col. 13, line 45).

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11. In regards to claims 9 and 10, the device further comprises an activity detector comprising an arrhythmia detector (col. 13, lines 21-40).

12. In regards to claim 61, the configuration instructions are received via telemetry (col. 2, line 2).

13. In regards to claim 65, the sensing circuit is adapted to sense an activity signal (col. 14, line 20).

14. In regards to claim 66, the device comprises a cardiac resynchronization device (118).

15. Additionally, claims 1, 61, 65, and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Lovett et al. (US 2004/0230229, hereinafter "Lovett").

16. In regards to claims 1 and 61, Lovett discloses a sensing circuit, pacing circuit, and processor (Fig. 5), wherein the sensing circuit is adapted to be programmed from far-field sensing to intracardiac sensing by telemetry programming the device (par. 0045).

17. In regards to claim 65, the device further comprises a physical activity sensor (par. 0130).

18. In regards to claim 66, the device further comprises a cardiac resynchronization device (par. 0049).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovett. Lovett discloses the essential features of the claimed invention including providing a microprocessor, memory circuit, activity sensor, electrogram storage, and arrhythmia detector (Fig. 5). Lovett does not expressly disclose that the control code is contained on RAM. It is well known in the art to store control code on RAM to allow the manipulation of control code by the device during operation to adapt to changing heart conditions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the control code of Lovett's invention on RAM to allow the manipulation of control code by the device during operation to adapt to changing heart conditions.

21. Claims 57-60 and 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine (or Lovett). Levine (or Lovett) disclose the essential features of the claimed invention including upgrading the device(s) via programming, but does not disclose a memory comprising a ROM portion and updatable/re-allocatable RAM portion, a safety operation mode during upgrading, configuration instructions comprising authorization information specific to the device being configured, or a configuration authorization module that generates a permission signal upon verification of

authorization information. It is well known in the art to provide implantable cardiac stimulators with a memory comprising a ROM portion and updatable/re-allocatable RAM portion to provide a memory that is resistant to corruption and still modifiable for adapting to the heart's changing conditions; a safety (or fallback) operation mode during telemetry to prevent life-threatening arrhythmia when the processor is busy with communication functions; and a handshake protocol specific to the device being configured to ensure that the instructions being telemetered to a device are appropriate for the specific device implanted in the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Levine's (or Lovett's) device with a memory comprising a ROM portion and updatable/re-allocatable RAM portion to provide a memory that is resistant to corruption and still modifiable for adapting to the heart's changing conditions; a safety (or fallback) operation mode during telemetry to prevent life-threatening arrhythmia when the processor is busy with communication functions; and a handshake protocol specific to the device being configured to ensure that the instructions being telemetered to a device are appropriate for the specific device implanted in the patient.

22. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine (or Lovett) in view of Morgan (US 5,024,221, hereinafter "Morgan"). Levine (or Lovett) disclose the essential features of the claimed invention except for band-pass filters having programmable filter coefficients with the claimed frequency ranges. Morgan teaches of providing a cardiac stimulator with a programmable band-pass filter (i.e. a first and second filter) to fit the frequency characteristics to the particular

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implantation (abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a cardiac stimulator with a programmable band-pass filter to fit the frequency characteristics to the particular implantation.

23. Further, Levine (or Lovett) in view of Morgan discloses the claimed invention but does not disclose expressly the claimed cutoff frequencies. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify filters as taught by Levine (or Lovett) in view of Morgan with the claimed cutoff frequencies because applicant has not disclosed that these frequencies provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the filters as taught by Levine (or Lovett) in view of Morgan because both filters effectively eliminate extraneous noise for a particular implantation configuration. Therefore, it would have been an obvious matter of design choice to modify Levine (or Lovett) in view of Morgan's cutoff frequencies to obtain the invention as specified in the claims.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lebel et al. (US 2002/0058906) is one of many teachings of a handshake operation with a specific implantable device and Smith, Jr. et al. (US 5,456,692) is one of many teachings of providing a safety mode during programming operations.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK


5/21/07


GEORGE R. EVANISKO
PRIMARY EXAMINER
5/21/07